## Title of Research Study: [insert title of research study here with protocol number, if applicable]

## Investigator: [insert name of principal investigator]

## Supported By: [List all monetary and non-monetary support for this research. If none, state, e.g., Northwestern University.] This research is supported by \_\_\_\_\_\_\_\_\_\_\_\_\_.

## Financial Interest Disclosure:

[Include if there is a financial interest to disclose. Otherwise delete.] The following disclosure is made to give you an opportunity to decide if this relationship will affect your willingness to participate in this research study:

## Why am I being asked to take part in this research study?

We are asking you to take part in this research study because \_\_\_\_\_\_\_\_\_\_\_\_\_. [Fill in the circumstance or condition that makes participants eligible for the research.]

## What should I know about a research study?

1. Someone will explain this research study to you.
2. Whether or not you take part is up to you.
3. You can choose not to take part.
4. You can agree to take part and later change your mind.
5. Your decision will not be held against you.
6. You can ask all the questions you want before you decide.

## Who can I talk to?

If you have questions, concerns, or complaints, or think the research has hurt you, talk to the research team at [Insert contact information for the research team]

This research has been reviewed and approved by an Institutional Review Board (“IRB”). You may talk to them at (312) 503-9338 or [irb@northwestern.edu](mailto:irboffice@organization.org) if:

1. Your questions, concerns, or complaints are not being answered by the research team.
2. You cannot reach the research team.
3. You want to talk to someone besides the research team.
4. You have questions about your rights as a research participant.
5. You want to get information or provide input about this research.

## Why is this research being done?

[Tell the participant the purpose of the research. Explain the background of the research problem. Explain any potential benefits to others.]

## How long will the research last?

We expect that you will be in this research study for \_\_\_\_\_\_\_\_ [hours/days/months/weeks/years, until a certain event]***.***

## How many people will be studied?

We expect about \_\_\_\_\_ people here will be in this research study out of \_\_\_\_\_ people in the entire study nationally [or internationally].

## What happens if I say “Yes, I want to be in this research”?

[Tell the participant what to expect using lay language and simple terms. Whenever appropriate include the following items:]

[

* A description of the procedures that will be performed. If practical, prepare a time-line chart or schematic to accompany descriptions of procedures and tests for research that require more than 1 or 2 steps/visits
* The length and duration of study visits, activities, and procedures
* With whom the participant will interact
* Where the research will be done
* When the research will be done
* List experimental procedures and therapies and identify them as such
* How often study activities and procedures will be performed
* What is being performed as part of the research study
* What is being performed as part of standard care (if the study involves any type of clinical care, e.g. mental health care)
* What procedures are part of regular medical care that will be done even if the participant does not take part in the research (if the study involves any type of clinical care, e.g., mental health care)
* When applicable indicate that the participants will be asked for permission to be contacted for future research.
* When applicable describe if audio or video recording any research activities. Include if agreement to be recorded is required for participation or if it is optional.

***]***

## What happens if I do not want to be in this research?

You can leave the research at any time and it will not be held against you.

[Include if there are alternatives other than participating. Otherwise delete.]Instead of being in this research study, your choices may include**:** [List alternatives procedures. For student participant pools describe alternatives for course credit. For clinical trials describe the options that you would normally offer patient. If applicable, include supportive care as an option.]

## What happens if I say “Yes”, but I change my mind later?

You can leave the research at any time and it will not be held against you.

[Include if there are potential adverse consequences to withdrawing from the research. Otherwise delete] If you decide to leave the research***,*** [Describe the adverse consequences.] If you decide to leave the research, contact the investigator so that the investigator can [Describe the procedures for orderly termination by the perticipant, if any.]

[Describe what will happen to data collected to the point of withdrawal. Describe whether participants will be asked to explain the extent of their withdrawal and whether they will be asked for permission to collect data through interaction or collection of private identifiable information. For example, a participant may wish to withdraw from the experimental procedure because of unacceptable side effects, but may agree to undergo follow-up procedures and data collection.]

## Is there any way being in this study could be bad for me?

[Delete this section if there are no risks or discomforts.]

[The risks of procedures may be presented in a table form.]

[Describe each of the following risks, if appropriate. If known, describe the probability and magnitude of the risk.]

* [Physical risks
* Psychological risks
* Privacy risks
* Legal risks
* Social risks
* Economic risks
* Group or community risks]

[Include for research that may result in additional costs to the participants. Otherwise delete.] Taking part in this research study may lead to added costs to you. [Describe what these costs are.]

[Include for Veterans Administration (VA) research. Otherwise delete.] You will not be required to pay for care received as a participant, except that some veterans are required to pay co-payments for medical care and services provided by Veterans Administration (VA) and that these co-payment requirements will continue to apply to VA-provided medical care and services that are not part of this study.

## Will being in this study help me in any way?

[Delete this section if there are no benefits.]

[Include if there are benefits to participation. Otherwise delete.] We cannot promise any benefits to you or others from your taking part in this research. However, possible benefits include \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_. [Then describe the potential benefits of participation. First describe any direct benefits to the participant, then any benefits to others. If benefits from participation may not continue after the research has ended, describe them here. Monetary reimbursement for participation is not a benefit.]

[Include for research involving prisoners]Taking part in this research study will not improve your housing or correctional program assignments. Your taking part in this research study will not improve your chance of parole or release.

## What happens to the information collected for the research?

Efforts will be made to limit the use and disclosure of your personal information, including research study and medical records, to people who have a need to review this information. We cannot promise complete secrecy. Organizations that may inspect and copy your information include the IRB and other representatives of this institution. [Add to this list other organizations that may have access to the participants records such as the US Department of Defense Health and Human Services, when the research is conducted or funded by DHHS, the sponsor, contract research organization, sponsor’s agent and other collaborating institutions.]

[Include one of the following Mandated or permitted Reporter Language statements if applicable. In studies in which researchers are probing for or likely to elicit information about child [or elder] abuse or neglect, the State of Illinois requires or permits researchers to report such information to authorities.] If we learn about current or ongoing child [or elder] abuse or neglect, we may be required or permitted by law or policy to report this information to authorities.

Or

An exception to our promise of confidentiality is when we in good faith are permitted by law or policy to report evidence of child [or elder] abuse or neglect.

Or

We will not ask you about child [or elder] abuse, but if you tell us about child [or elder] abuse or neglect, we may be required or permitted by law or policy to report to authorities.

[Describe any other limitations on confidentiality based on possible legal issues. For example, if the research team is likely to uncover drug use or other sensitive information (like HIV diagnosis), explain that this information may be disclosed to appropriate authorities.]

[Include the following statement if the research is being conducted under a Certificate of Confidentiality. Otherwise delete.] In this study, you will be asked about illegal activities or highly personal behavior. We have obtained a Certificate of Confidentiality from the federal government. However, we may still be required under certain circumstances to release your information.

[If data or specimens will be retained after the study for future research, explain where the data or specimens will be stored, who will have access to the data or specimens, and how long the date or specimens will be retained.]

[Include for research where the sponsor may pay for medical expenses of the participant.] If the sponsor pays any of your medical expenses, we may be required to give the sponsor your name, date of birth, and Medicare ID or social security number.

[Include for research involving prisoners. Otherwise delete.] If you are a prisoner, your medical records may also be given to officials and agencies within the criminal justice system when necessary and permitted by law.

## Can I be removed from the research without giving my OK?

[Delete this section if not applicable.]

[Include for research where this is a possibility. Otherwise delete.] The person in charge of the research study or the sponsor can remove you from the research study without your approval. Possible reasons for removal include [describe reasons why the participants may be withdrawn, if appropriate.]

[Include for research where this is a possibility. Otherwise delete.] We will tell you about any new information that may affect your health, welfare, or choice to stay in the research.

## What else do I need to know?

[Include for research involving more than minimal risk. Otherwise delete.]If you need medical care because of taking part in this research study, please seek medical treatment through the investigator or a treatment center of your choice. If you seek treatment from someone other than the investigator, contact the investigator to inform [her/him] about any related injury or illness. Generally, this care will be billed to you, your insurance, or other third party. [Insert the name of the institution] has no program to pay for medical care for research-related injury. [Describe any compensation available for research related injury.]

[For studies taking place in a school, this paragraph must be included:]

Parents please be aware that under the Protection of Pupils Right Act 20 U.S.C. Section 1232 (c)(1)(A), you have the right to review a copy of the questions asked of or materials that will be used with your students. If you would like to do so, you should contact [Principal Investigator] to obtain a copy of the questions or materials.

[Include if participants will be paid. Otherwise delete.] If you agree to take part in this research study, we will pay you \_\_\_\_\_\_\_\_ [indicate amount]for your time and effort. [Indicate if the amount is pro-rated for research visit completion.]

[Include for Department of Defense (USDOD) research that targets military personnel where participants will be paid. Otherwise delete.] Military personnel should check with their supervisor before accepting payment for participation in this research.

[Include for research involving prisoners where there may be a need for follow-up examination or care after the end of participation. Otherwise delete.] If you are released from jail before you finish this research study, you should take steps to get insurance or Medicaid coverage. Regular office visits and standard treatment will be billed to you or your health insurance. You may continue in the research study after your release from prison. If you move out of the area, we will help you make arrangements to be followed by a physician.

[When applicable indicate that the investigator believes that the biologic specimens obtained could be part of or lead to the development of a commercial product.]

[When applicable indicate when and how the participant will be informed of the results of the research.]

## HIPAA Authorization

[Includes “HIPAA Authorization” section from “Biomedical Template Consent Document (HRP-502x)” if required. Otherwise delete this section.]

## Optional Elements:

[Include for any optional elements of the research. Otherwise delete.] The following research activities are optional, meaning that you do not have to agree to them in order to participate in the research study. Please indicate your willingness to participate in these optional activities by placing your initials next to each activity.

|  |  |  |
| --- | --- | --- |
| I agree | I disagree |  |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_ | The researcher may audio or video record me to aid with data analysis. The researcher will not share these recordings with anyone outside of the immediate study team. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_ | The researcher may audio or video record me for use in scholarly presentations or publications. My identity may be shared as part of this activity, although the researcher will attempt to limit such identification. I understand the risks associated with such identification. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_ | The researcher may contact me in the future to see whether I am interested in participating in other research studies by the principal investigator of this study. |
| \_\_\_\_\_\_\_ | \_\_\_\_\_\_\_\_ | The researcher may retain any leftover blood or tissue samples taken during the study. These samples may be used for other research not related to this study. These samples will be retained in non-identifiable form, meaning that there will be no information associated with the blood or samples that will allow anyone to readily ascertain my identity. |

[There are three sets of signature options listed below. Use the signature block appropriate for your study. Delete those that do not apply. Omit the signature page if there is no written documentation of consent.]

Signature Block for Capable Adult

Your signature documents your permission to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

[Add the following if a witness will observe the consent process. e.g., short form of consent documentation or participants unable to read.]

My signature below documents that the information in the consent document and any other written and information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person witnessing consent process

Signature Block for Adult Unable to Consent

Your signature documents your permission for the named participant to take part in this research.

Your signature documents your permission to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of participant Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of participant

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of person obtaining consent Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person obtaining consent

[Add the following if you will document assent of the participant.]

Assent:

[ ] Obtained verbally without a signature

[ ] Not obtained because the capability of the participant is so limited that the participant cannot reasonably be consulted.

[Add the following if a witness will observe the consent process. E.g., short form of consent documentation or illiterate participants.]

My signature below documents that the information in the consent document and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person witnessing consent process

**Signature Block for Parent permission and Child Assent**

Your signature documents your permission for the named child to take part in this research.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of child Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of child

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of parent [ ] or individual legally authorized [ ] Date

to consent for the child to participate

Note: Investigators are to ensure that individuals who are not parents can demonstrate their legal authority to consent to the child’s participation in the research. Contact legal counsel if any questions arise.

If signature of second parent not obtained, indicate why: (select one)

[ ] The IRB determined that the permission of one parent is sufficient.

[ ] Second parent is: [ ] deceased [ ] unknown [ ] incompetent [ ] not reasonably available

[ ] Only one parent has legal responsibility for the care and custody of the child

[Add the following block if you will document assent of children]

Assent:

[ ] Obtained verbally without a signature

[ ] Not obtained because the capability of the child is so limited that the participant cannot reasonably be consulted.

[Add the following if a witness will observe the consent or assent process. E.g., short form of consent documentation or illiterate participants.]

My signature below documents that the information in the consent document and assent process and any other written and verbal information was accurately explained to, and apparently understood by, the participant, and that consent was freely given by the participant.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature of witness to consent/assent process Date

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Printed name of person witnessing consent/assent process